

Insulin in America: A Right or a Privilege?

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Even as a medical student, I was interested in the history of insulin. As an endocrine fellow, I read *The Discovery of Insulin* by Michael Bliss (1). It is a book anyone interested in diabetes should read, as life before insulin is difficult to appreciate by today's standard of care, at least in the United States. Amazing stories of what people did to obtain insulin are plentiful, perhaps none more dramatic than Eva Saxl's story, with her husband making insulin in Shanghai, China, for the more than 200 Jews who escaped Nazi persecution during World War II (2).

But in the United States, access to insulin had never been a problem. As a medication required for survival by 10% of those with diabetes, it was always available, although for decades quite crude by today's standards. The insulin patent from the University of Toronto was sold for \$1 with the understanding that cheap insulin would become available (3). Through the years, insulin remained affordable. Even with the introduction of human insulin in 1982 (\$14 per vial) and then insulin analogs in 1996 (\$24 per vial), the increases in insulin pricing did not seem to be a concern. At least in the United States, the vast majority of patients requiring insulin had access to all of the insulin analogs as they were developed.

As the years passed, the cost of insulin continued to increase. In 2004, I was asked to write a review of insulin analogs, which was published in early 2005 (4). Just before publica-

tion, one of the reviewers asked me to publish the costs of the insulin products. In those days, we used the Web site drugstore.com to compare prices, and, in general, vials of insulin analogs cost ~\$60 each. Although this represented a substantial price increase since the introduction of insulin lispro in 1996, patients generally could still afford their insulin, and the copayments for those who had commercial insurance were quite reasonable. However, for those without any insurance (16.4% in 2005 compared to 10.7% in 2015 [5]), these prices were problematic. What I remember most about that article is that a representative of one of the insulin companies contacted me, quite upset that I would dare to publish this information. I was told that drugstore.com, obviously a very public online venue, did not reflect what most patients pay for their insulin and that I should learn more about the economics of insulin pricing.

Little could anyone have predicted what would happen a decade later. In 2012, I was asked to participate in a debate on insulin pricing, taking the "pro" side that insulin analogs were worthy of their costs. At the time, vials of insulin lispro and insulin glargine were \$138 and \$125, respectively (again, based on drugstore.com). At the time, this represented 134 and 116% increases in price, respectively, since 2005. My argument focused on a complex discussion of the health economics of hypoglycemia in type 1 diabetes. (It was more

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difficult to use this argument for type 2 diabetes.) Still, on my conclusion slide, I noted that, “Whether we like it or not, many of our patients in the U.S. will be forced to ‘go back in time’ to human insulin due to the fact that the payers and the patients themselves cannot afford insulin analogs.” I also told the audience that I had heard from a friend inside one of the insulin companies to expect that same vials of insulin to exceed the \$200 mark in the not-too-distant future. Most of the audience rolled their eyes at me.

Meanwhile, the worldwide insulin market exploded. A \$7.3 billion business in 2005 achieved a \$21 billion global market by 2013, mostly as a result of the U.S. health care system’s “willingness to pay for modest differentiation and its acceptance of repeated price increases” (6). The United States was (and is) paying a disproportionate amount for insulin, and although there are many complex reasons for this, the most important one is simply because there are no real price controls, as one would see in the government-run systems of Canada, the United Kingdom, Germany, or virtually any other country. In fact, although North America accounts for 7% of the world’s diabetes, it accounts for 52% of global insulin sales (6). China, by comparison, accounts for 25% of the world’s diabetes but for only 4% of global insulin sales.

In the past few years, the price of insulin has become more than a casual interest, and it has become clear to me for the first time that patients of mine are having difficulty affording their insulin. This is especially true for Medicare patients in the “donut hole” and those without any insurance, but most surprising is the fact that many patients with commercial insurance now have astronomically high copayments.

Because of the patient population in our hospital (a “disproportionate share” hospital), we had had a 340B drug pricing program from the federal government. This had allowed my patients (with or without

insurance) to obtain their insulin at extremely low prices. Through this program, patients paid less than their copayments for their insulin—often several hundred dollars less for a 3-month supply. However, we lost this program in early 2016, and now patients have to pay full retail prices. One woman on an insulin pump noted after she went to pick up her insulin and had to pay the full retail price that “my insulin now costs more than my home mortgage.”

This, to me, seems like a crisis. Patients literally need to decide if they will pay for their insulin or for their housing and food. And for patients with type 1 diabetes, there are not many options. Although I acknowledge that the various patient assistance programs can be helpful and are underutilized (but also add a major level of difficult bureaucracy to the system), wouldn’t it make more sense to make the pricing more reasonable in the first place?

In early 2015, I was asked to give a talk about insulin pricing in the United States as part of a symposium at the American Diabetes Association (ADA) Scientific Sessions in Boston, Mass. Little could I have imagined the impact that single talk would make on everyone who heard it. The most interesting comment I heard repeatedly after the talk was how “brave” I was to give such a transparent talk against the insulin companies. In reality, at the time, I did not have a good understanding of how the various “middlemen” or “drug channel companies” (pharmacy benefit managers [PBMs], wholesalers, and chain pharmacies) could affect final prices to patients. An article written by Kasia Lipska and published in the *New York Times* earlier this year provides an important lesson about how PBMs work (7). Dr. Lipska noted that the three largest PBMs bring in more than \$200 billion per year in revenue and further explained how the “rebates” from the drug companies “look suspiciously similar to kickbacks.” Another excellent review of

this complex system was published recently in *Diabetes Forecast*, the ADA magazine for people with diabetes (8).

So where does all of this leave us now? We were recently told that insulin pricing increased threefold between 2002 and 2013 and that the expenditure for insulin per patient in the United States was greater than for all other antihyperglycemic medications combined (9). As a society, how do we rationalize the fact that this elixir, required for survival by ~1.5 million people and used by another 4.5 million in the United States, has become unaffordable for many? Is this what the original group from the University of Toronto wanted in 1922? I know this was never the goal of Eli Lilly at that time (10).

I would suggest that insulin is not like a sodium-glucose cotransporter 2 inhibitor or a glucagon-like peptide 1 receptor agonist. It is not a concierge drug that should be used only by those who can afford it. Insulin, in my view, is a right, not a privilege. And although I have no problems with the newest and “greatest” insulins receiving whatever cost the market can bear, older insulins—yes, including the insulin analogs—ideally should be made available for all Americans at a reasonable cost.

This concept may seem counterintuitive for many in the United States and perhaps (for insulin anyway) would make us look more like our neighbors and our friends in Europe. But to those who detest the thought of having our government involved in the distribution of insulin, I would say that I detest more the pain, suffering, cost, and potential death from diabetic ketoacidosis resulting from patients’ inability to afford insulin. Insulin should be readily available to anyone who needs it.

Duality of Interest

Dr. Hirsch is a consultant for Abbott Diabetes Care, Intarcia, and Roche Pharmaceuticals. No other potential conflicts of interest relevant to this article were reported.

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